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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/549,914 | 09/20/2005 | Yasumi Yugari | 2005_1461A | 4790 |
| 513 | 7590 | 06/05/2009 | EXAMINER | |
| WENDEROTH, LIND & PONACK, L.L.P. 1030 15th Street, N.W., Suite 400 East Washington, DC 20005-1503 | | | FRAZIER, BARBARA S | |
| ART UNIT | | PAPER NUMBER | | 1611 |
| MAIL DATE | | DELIVERY MODE | | 06/05/2009 PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/549,914 | YUGARI ET AL. | |
| | Examiner | Art Unit | |
| | BARBARA FRAZIER | 1611 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 12 February 2009 and 12 March 2009.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1 and 3-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1 and 3-10 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/12/09 has been entered.

Status of Claims

2. Claims 1 and 3-10 are pending in this application. Cancellation of claim 2 is acknowledged.

3. Claims 1 and 3-10 are examined.

Specification

4. The objection to the disclosure is withdrawn in view of Applicant's amendment to the disclosure.

Response to Arguments

5. Applicant's arguments filed 2/12/09 have been fully considered but they are not persuasive.

In response to Applicant's argument that the "metal-containing yeast" limitation of claim 1, as currently amended, is not disclosed or suggested by prior art, said argument has been considered but is deemed to be moot in view of the new grounds of rejection, set forth below.

In response to Applicant's argument that "lowering the concentration of nitrogen in the blood" with the food composition of the present invention is not disclosed or suggested in the prior art, the phrase "for lowering the concentration of nitrogen in the blood" recites an intended use for the food composition and does not recite a structural limitation for the composition, and thus is not given patentable weight.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. The rejection of claims 1-10 under 35 USC 103(a) as being unpatentable over Nakashima et al (US Patent 5,126,143) in view of Farmer (US Patent 6,461,607) is moot in view of Applicant's amendment to claim 1 and the new grounds of rejection, set forth below.
8. **Claims 1 and 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakashima et al (US Patent 5,126,143) in view of Farmer (US Patent 6,461,607) and Greenberg (US Patent 5,260,279).**

The claimed invention is drawn to a food composition for lowering blood concentration of low- molecular-weight nitrogen-containing compounds, which

comprises: a foodstuff with a) more than 5% by weight of water-soluble indigestible polysaccharides relative to a total amount of dried foodstuff, said indigestible polysaccharides capable of being decomposed by intestinal bacteria, and b) *Bacillus coagulans*, said foodstuff having metal-containing yeast of 0.01% to 5.0% by weight and protein component of 8% or less by weight (see claim 1).

Nakashima et al teach a bowel-movement-improving food containing 10-50% by weight of dietary fibers based upon the whole product (see claim 1). Nakashima et al. teach foods having more than 5% by weight indigestible polysaccharides; see Example 1, which has 25% dietary fibers (18 parts polydextrose and 6.9 parts pectin, relative to 100.3 total parts). The amount of protein in the food is less than 8%; amounts of 6% and 5.4% casein are exemplified (see, for example, Examples 1 and 4). The dietary fibers are decomposed by intestinal microorganisms (see Examples 1, 4 and 5).

Nakashima et al do not specifically teach the presence of *Bacillus coagulans* or metal containing yeast of 0.01% to 5% by weight in the food composition.

Farmer teaches the utilization of lactic acid-producing bacteria, preferably *Bacillus coagulans*, for control of gastrointestinal tract pathogens and their associated diseases (abstract), and that *Bacillus coagulans* strains have been used as general nutritional supplements and agents to control constipation and diarrhea in humans and animals (col. 14, lines 50-53).

Greenberg teaches a feeding composition which contains soluble fiber, such as pectin (a water-soluble indigestible polysaccharide; see abstract). These compositions comprising soluble fiber may contain metal-containing yeast; selenium yeast and

chromium yeast are exemplified in a total amount of 0.01534% (see Example 3), which falls within Applicant's range of 0.01 to 5% by weight. The composition provides nourishment to colon cells and also aids in preventing diarrhea (abstract).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add *Bacillus coagulans* and metal-containing yeast to the composition of Nakashima et al; thus arriving at the claimed invention. One skilled in the art would have been motivated to do add *Bacillus coagulans* because the addition of *Bacillus coagulans* provides the benefits of controlling constipation and diarrhea, as taught by Farmer. Additionally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art, to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. See MPEP 2144.06. Additionally, since the addition of metal containing yeast is known to be useful in nutritional compositions containing soluble fiber, as taught by Greenberg, one skilled in the art would be motivated to add metal containing yeast in order to provide additional nutritional benefits, as well as providing the benefit of preventing diarrhea, as taught by Greenberg. One would reasonably expect success from the addition of *Bacillus coagulans* as taught by Farmer and metal containing yeast as taught by Greenberg to the composition taught by Nakashima et al because all of the references are drawn to improving bowel movements.

Regarding the phrase "for lowering blood concentration of low-molecular-weight nitrogen-containing compounds", said phrase describes an intended use for the food

and does not provide any structural limitation to the composition, and thus is not given patentable weight.

Regarding claim 3, Nakashima et al. disclose that dietary fibers which may be used are polydextrose and pectin (see col. 3, lines 20-22 and claim 1).

Regarding claim 4, Nakashima et al. disclose that the food contains a mixture of polydextrose and pectin, wherein said mixture is comprised of 1/2 to 3/4 polydextrose and 1/2 to 1/4 pectin. This reads on Applicant's ratio of 0.05 to 100 parts by weight of pectine to 100 parts of polydextrose.

Regarding claims 5 and 6, Nakashima et al. disclose that the foods may contain vitamins (col. 4, lines 32-38).

Regarding claims 7-10, Nakashima et al. disclose that the food may be in the form of the wafer; the term "wafer" reads on a reasonable interpretation of either "biscuit", "cookie" or "bread".

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611